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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,928	01/21/2005	Ajay S Bhatnagar	ON/4 - 32602A	6202
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NOVARTIS				
CORPORATE INTELLECTUAL PROPERTY				
ONE HEALTH PLAZA 104/3				
EAST HANOVER, NJ 07936-1080				
EXAMINER				
JAVANMARD, SAHAR				
ART UNIT		PAPER NUMBER		
1627				
MAIL DATE		DELIVERY MODE		
11/25/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/521,928

**Applicant(s)**

BHATNAGAR ET AL.

**Examiner**

SAHAR JAVANMARD

**Art Unit**

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18, 19, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

Claim(s) 18-19 and 23-24 are pending and are examined herein.

### ***Response to Arguments***

Applicant arguments with respect to the 103(a) rejection of claims 18, 19, and 23-24 as being unpatentable over Freyer et al. in view of Reid (N. Engl. J. Med., 2002) and Iqbal (*Expert Opin. Pharmacother.*) have been fully considered. Upon further examination of the claims, it is Examiners opinion that the claims in question are essentially drawn to a method of treating bone loss in a patient with zoledronic acid. Although the claims set forth that the patient is receiving letrozole, this is not the issue at hand. The claim is examined on the method of treatment and the composition that is administered, how the bone loss arises is considered to be part of the preamble and is not given patentable weight. Said rejection is hereby withdrawn and a new rejection is made of record in the office action below. In order to give Applicant an opportunity to respond to the new rejection, the office action has been made non-final.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-19 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reid (N. Engl. J. Med., 2002) and Coleman (*Breast Cancer*, 2000).

Reid teaches administering in zoledronic acid to postmenopausal women with low bone density (page 654, methods). Reid further teaches that zoledronic acid is the most potent bisphosphonate that has been studied in clinical trials to date. Reid further teaches that zoledronic acid is superior to pamidronate in the treatment of cancer-related hypercalcemia. Additionally, Reid teaches that because of its high potency, only small doses are required for the inhibition of bone resorption, and long dosing intervals may be used (page 654, lines 1-6), including administering zoledronic acid at base line and again at six months (page 654, see Treatment).

Coleman teaches the role of bisphosphonates, namely zoledronic acid, in metastatic bone disease and their use in the treatment of osteoporosis in cancer patients (abstract, whole document).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the methods of Reid in treating bone loss in patients suffering from bone loss disorders such as osteoporosis to have also treated patients suffering from bone loss that arises as a result of receiving letrozole. Although Reid does not teach that the patients administered zoledronic acid are suffering from bone loss resulting from the administration of letrozole, one of ordinary skill in the art would find it obvious to treat the bone loss regardless of the cause of the bone loss. Thus whether a patient is need of zoledronic acid because of osteoporosis arising menopause or bone loss as a result of the side effect of an antineoplastic treatment agent, the administration of zoledronic acid is obvious and the cause, as viewed by Examiner, is beside the point.

### ***Conclusion***

Claims 18-19 and 23-24 are not allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./  
Examiner, Art Unit 1627

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1627